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21 NORTHERN DISTRICT OF CALIFORNIA
22 SAN FRANCISCO DIVISION
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25 IN RE CONNETICS CORP.
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1 **I. INTRODUCTION**

2 Plaintiff admits that the Court may take judicial notice of all but six of the 41 exhibits
 3 submitted by Connetics in support of its motion to dismiss. The remaining six exhibits – four
 4 public records from the FDA (Exhibits 30 to 33) and two summary exhibits (Exhibits 39 and
 5 40) – are also subject to judicial notice. The FDA records fall squarely within the ambit of Rule
 6 201 of the Federal Rules of Evidence. The contents of these documents are capable of accurate
 7 and ready determination by resort to sources whose accuracy cannot reasonably be questioned.
 8 Fed. R. Evid. 201. The two summary exhibits may also be considered. They are accurate
 9 summaries of other voluminous and judicially noticeable facts. There is no legitimate reason to
 10 ignore them. *See* Fed. R. Evid. 1006 (allowing summaries of voluminous documents).

11 Plaintiff ignores the governing legal standard and instead argues that the Court should not
 12 consider the FDA public records because, according to plaintiff, they are not “central” to its
 13 claim. RJN Opp. at 9. However, the law does not impose a “centrality” test. In any event, the
 14 FDA public records go to the heart of plaintiff’s claims because they show that the FDA approved
 15 dermal products with benzoyl peroxide even though that substance “induced skin tumors in
 16 transgenic Tg.AC mice.” Steskal Decl. Ex. 30. Connetics was aware of, and relied on, the
 17 FDA’s past decisions relating to such products when it projected that Velac could be approved by
 18 the FDA. *Id.* Ex. 1, at 6. The FDA public records refute any inference that defendants intended
 19 to mislead investors about Velac’s prospects for approval. *See In re Vertex Pharms., Inc. Sec.*
 20 *Litig.*, 357 F. Supp. 2d 343, 352 (D. Mass. 2005) (taking judicial notice of FDA public records
 21 and holding that undisclosed preclinical animal test did not foreclose prospects of FDA approval
 22 because other products had been approved that showed toxicity in same preclinical test).

23 Plaintiff expends most of its opposition arguing that although the Court may take judicial
 24 notice of many of the exhibits, it should then disregard those exhibits whenever plaintiff asserts in
 25 conclusory fashion that the facts are “hotly contested.” RJN Opp. at 4. Not surprisingly,
 26 plaintiff’s nonsensical argument is contrary to the law. *Tellabs* makes clear that a court **must**
 27 consider ***all the facts alleged*** including, “in particular, documents incorporated into the complaint
 28 by reference, and matters of which a court may take judicial notice.” *Tellabs v. Makor Issues &*

1 *Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007). In addition, “in determining whether the pleaded facts
 2 give rise to a ‘strong’ inference of scienter, the court ***must take into account plausible opposing***
 3 ***inferences,***” that is, “plausible nonculpable explanations for defendants’ conduct.” *Id.* at 2509-10
 4 (emphasis added). When undertaking this “inherently comparative” inquiry, a court must weigh
 5 competing inferences and determine whether plaintiff has met its burden of pleading a “cogent
 6 and compelling” inference of scienter, which is an inference that is “more than merely plausible
 7 or reasonable.” *Id.* at 2504-05, 2510.

8 Plaintiff’s argument would foreclose the very analysis that is compelled by the Reform
 9 Act and *Tellabs*. Whereas the Reform Act and *Tellabs* require a court to consider judicially
 10 noticeable facts and draw inferences from those facts that are favorable to the defendants, plaintiff
 11 argues that this Court should disregard such facts whenever defendant disagrees with (*i.e.*,
 12 “disputes”) those inferences. RJD Opp. at 4. If accepted, the Court would be left with nothing to
 13 consider but the “facts” plaintiff selectively highlights and the inferences that plaintiff urges.
 14 That is precisely the legal standard that the Reform Act and *Tellabs* rejected. Moreover, the
 15 Reform Act is clear that a plaintiff cannot allege a securities fraud claim merely by stating in
 16 conclusory fashion, as plaintiff does here, that a statement or fact is “false” or “hotly contested.”
 17 *Id.* Rather, a plaintiff must plead facts with particularity demonstrating the reasons why the
 18 statement or fact is false. 15 U.S.C. § 78u-4(b)(1); *In re Silicon Graphics Inc. Sec. Litig.*, 183
 19 F.3d 970, 984 (9th Cir. 1999) (“[W]e read the statutory command that a plaintiff plead all the
 20 ‘facts’ with ‘particularity’ to mean that a plaintiff must provide a list of all relevant circumstances
 21 in great detail”).

22 Plaintiff is also wrong when it contends that the Court cannot consider the documents at
 23 issue for the truth. RJD Opp. at 1. This proposition is directly contradicted by the very authority
 24 relied on by plaintiff in its opposition. See *In re CV Therapeutics, Inc. Sec. Litig.*, 2004
 25 WL 1753251, *12 (N.D. Cal. Aug. 5, 2004) (“Finally, plaintiffs argue that the Court cannot
 26 consider any documents for the ‘truth of their contents.’ The Court does not restrict its taking of
 27 judicial notice in this way.”) (citations omitted); see also Fed. R. Evid. 803(8) (public records are
 28 not hearsay and may be considered for truth). In any event, even if the Court does not consider

1 the documents at issue for the truth, the Court must consider the documents when determining
 2 whether plaintiff has pleaded a “cogent and compelling” inference of scienter. That means that if
 3 the contents of a judicially noticeable document or a document cited in the complaint refutes an
 4 inference of scienter, the Court must consider that document and dismiss plaintiff’s complaint.
 5 *See Tellabs*, 127 S. Ct. at 2509-10 (requiring court to examine judicially noticeable documents
 6 and documents incorporated by reference and to engage in comparative analysis that credits
 7 inferences favorable to defendants); *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002)
 8 (holding that court “must consider . . . inferences unfavorable to the plaintiffs” and dismissing
 9 complaint where allegations negated a strong inference of scienter); *In re Applied Micro Circuits*
 10 *Corp. Sec. Litig.*, 2002 U.S. Dist. LEXIS 22403, *12 (S.D. Cal. Oct. 3, 2002) (holding that court
 11 must consider entire contents of SEC filings selectively quoted in complaint for purpose of
 12 drawing inferences relating to plaintiff’s allegations).

13 **II. THE COURT SHOULD TAKE JUDICIAL NOTICE OF FDA RECORDS**

14 Plaintiff objects to Exhibits 30 to 33, public records available from the FDA’s website.
 15 However, plaintiff fails to articulate any reason why the Court should not take judicial notice of
 16 these records under Rule 201. Exhibits 30 to 33 are neither subject to reasonable dispute nor can
 17 their accuracy be questioned. The law is clear that courts routinely take notice of records and
 18 reports of administrative bodies, such as the FDA. *See Metro Pub., Ltd. v. San Jose Mercury*
 19 *News*, 987 F.2d 637, 641 n.3 (9th Cir. 1993) (taking judicial notice of trademark registrations);
 20 *Interstate Natural Gas Co. v. Southern California Gas Co.*, 209 F.2d 380, 384-85 (9th Cir. 1953)
 21 (taking judicial notice of contract and rates filed with federal agency); *In re Wellbutrin SR/Zyban*
 22 *Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003) (taking judicial notice of FDA
 23 report posted on FDA website).

24 Plaintiff wrongly contends that the court cannot take judicial notice of Exhibits 30 through
 25 33 because they are not “central” to plaintiff’s claim or “referenced” in the complaint. RJD Opp.
 26 at 9. That is not the standard. Rather, a court can take judicial notice of FDA public records in a
 27 securities fraud case because such records are available to and relied upon by the investing public
 28 and provide context for plaintiff’s allegations. *See Vertex Pharms.*, 357 F. Supp. 2d at 352 n.4

1 (taking judicial notice of FDA public records); *In re Guidant Corp. Sec. Litig.*, 2006
 2 WL 2538374, *9 n.20 (S.D. Ind. Nov. 8, 2004) (same). Notably, plaintiff does not dispute that
 3 the Court can take judicial notice of similar documents under the same legal doctrine, including
 4 the FDA's Manual of Policies and Procedures (Exhibits 28 and 29) and various analyst reports
 5 (Exhibits 35 through 37). Given the lack of any objection to such documents, it is clear that
 6 plaintiff's objections here are not based on principle, but on a thinly cloaked desire to distract the
 7 Court from considering public records that are devastating to plaintiff's allegations of fraud.

8 In any event, plaintiff is wrong when it argues that FDA records are not "central" to its
 9 claim. The gravamen of plaintiff's claim is that defendants made optimistic statements about
 10 Velac's prospect for approval when, according to plaintiff, they knew all along that approval
 11 could not be obtained. The FDA records establish that defendants reasonably believed that Velac
 12 could be approved despite the results of the Tg.AC mouse study. For example, Exhibit 30 is the
 13 FDA approval label for BenzaClin (which includes benzoyl peroxide):

14 **BenzaClin™ Topical Gel**
 15 (clindamycin - benzoyl peroxide gel)

Rx Only

16 **Topical Gel: clindamycin (1%) as clindamycin phosphate, benzoyl peroxide (5%)**
 17 **For Dermatological Use Only - Not for Ophthalmic Use**
Reconstitute Before Dispensing

18 **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Benzoyl peroxide has been
 19 shown to be a tumor promoter and progression agent in a number of animal studies. The
 20 clinical significance of this is unknown.

21 Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced
 22 skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment.

23 This FDA public record demonstrates that dermal products that include benzoyl peroxide have
 24 been approved by the FDA despite adverse Tg.AC test results: "Benzoyl peroxide . . . induced
 25 skin tumors in transgenic Tg.AC mice." Far from foreclosing the possibility of FDA approval for
 26 BenzaClin, the adverse Tg.AC test results were simply included as part of the BenzaClin label.

27 Other courts have taken judicial notice of similar records and held that they are highly
 28 relevant in evaluating whether a plaintiff has met its burden of pleading a strong inference of

1 scienter. For example, in *Vertex Pharms.*, the plaintiff alleged that defendants misrepresented the
 2 prospects for a drug's approval and made false and misleading statements regarding the results of
 3 Phase I and II clinical studies because the defendants failed to disclose that preclinical animal
 4 tests showed that the drug was "dangerously toxic." The court dismissed plaintiff's complaint:

5 [T]he allegation that the defendants were aware that preclinical testing
 6 demonstrated a toxicity problem with VX-745 by March of 1999 is not in itself
 7 sufficient to demonstrate scienter. The fact that a drug has a certain toxicity level
 8 does not necessarily doom the drug's commercial prospects. As defendants point
 9 out, many drugs currently on the market are toxic depending on dosage levels and
 10 concentrations. Defendants note that other drugs (such as Lipitor and Zocor) have
 been found in animal studies to have toxic effects on the CNS in certain dosages,
 yet have been approved by the FDA. *See Def.'s Exh. I, J.* Thus, defendants'
 knowledge of some toxicity in VX-745 in 1999, without more, is insufficient to
 indicate "a mental state embracing intent to deceive, manipulate, or defraud.

11 357 F. Supp. 2d at 352 (case citation omitted). The same analysis applies here. The fact that
 12 Velac showed a positive response in the Tg.AC model did not "doom the drug's commercial
 13 prospects." *Id.* As shown by the FDA public records relating to BenzaClin, other dermal
 14 products have shown a positive result in that model but were nonetheless approved by the FDA.
 15 As such, the FDA documents are exactly the type of judicially noticeable records that the Court is
 16 required to consider under *Tellabs* because they refute an inference of scienter.

17 Plaintiff is also wrong when it argues that the Court should not consider the contents of
 18 Exhibits 30 through 33 because the documents are not "referenced" in its complaint. RJD Opp.
 19 at 9. As shown, that fact has no legal significance because a court is required to consider
 20 judicially noticeable documents, even if not referenced in the complaint. *Tellabs*, 127 S. Ct. at
 21 2509. In any event, the complaint quotes at length from documents that demonstrate that (1)
 22 defendants were aware that the FDA had approved dermal products with benzoyl peroxide even
 23 though that compound "induced skin tumors in transgenic Tg.AC mice" and (2) defendants relied
 24 on those FDA decisions when they determined that Velac could be approved. For example, the
 25 complaint specifically calls out, quotes from, and relies on Connexis' April 26, 2005 conference
 26 call regarding the Tg.AC mouse study. *See AC ¶¶ 261-265.* During that conference call,
 27 Connexis specifically referred to drugs such as BenzaClin that also have had positive Tg.AC test
 28 results to explain why they believed Velac could be approved. Ex. 1 at 6, 24; *see infra* at 9.

1 Plaintiff attempts to avoid the import of the April 26, 2005 conference call by literally
 2 deleting from the quotations in its complaint the portions that refer to the FDA approval of dermal
 3 products with benzoyl peroxide. *Compare* AC ¶ 261 (“ . . . ”) with Ex. 1, at 6 (“benzoyl peroxide,
 4 a commonly used OTC acne product and an ingredient in several prescription acne products, has
 5 Rx labeling that notes a positive result in this model”). However, despite plaintiff’s self-serving
 6 attempt to edit the statement, the law is clear that when a plaintiff selectively quotes from a
 7 document, the court must consider the entire document. *See Osher v. JNI Corp.*, 308 F. Supp. 2d
 8 1168, 1186 (S.D. Cal. 2004), *aff’d in relevant part*, 183 Fed. Appx. 604 (9th Cir. 2006) (court
 9 must consider full document, not just portions plaintiff “selectively quote”); *Reiger v. Altris
 10 Software, Inc.*, 1999 WL 540893, *2 (S.D. Cal. Apr. 30, 1999) (“the court may consider the full
 11 text of those documents, even when the complaint quotes only selected portions.”); *In re
 12 Harmonic, Inc. Sec. Litig.*, 163 F. Supp. 2d 1079, 1084 (N.D. Cal. 2001) (defendants may “attach
 13 to a 12(b)(6) motion the documents referred to in the complaint to show that they do not support
 14 plaintiff’s claim.”).

15 Plaintiff also attempts to distract the Court from the import of the FDA public records by
 16 arguing that the facts relating to the approval of benzoyl peroxide are “highly disputed.” RJD
 17 Opp. at 10. However, plaintiff never explains what exactly it disputes about those facts, nor does
 18 it make any allegations in its complaint demonstrating with the requisite particularity that
 19 defendants misrepresented those facts. For instance, plaintiff does not allege – nor could it – that
 20 dermal products with benzoyl peroxide were not approved by the FDA despite the fact that
 21 benzoyl peroxide “induced skin tumors in transgenic Tg.AC mice.” Plaintiff also does not allege
 22 – nor could it – that defendants were unaware of the FDA’s decision to approve those products
 23 and did not rely on that decision when they projected that Velac could be approved. At bottom,
 24 plaintiff’s quarrel is not with the judicially noticeable facts, but with the inferences that
 25 defendants draw from those facts: namely, that defendants reasonably concluded that Velac
 26 might be approved. Under *Tellabs*, the Court must consider those inferences, and dismiss the
 27 complaint where (as here) it eviscerates any “cogent and compelling” inference of scienter. *See*
 28 *Vertex Pharms.*, 357 F. Supp. 2d at 352.

1 **III. THE COURT SHOULD TAKE JUDICIAL NOTICE OF SUMMARY EXHIBITS**

2 Plaintiff also objects to Exhibits 39 and 40. These are summaries of what plaintiff
 3 acknowledges are judicially noticeable facts. Such summaries are offered merely as a
 4 convenience to the Court, and the Court may properly consider them. *See, e.g., DeMarco v.*
 5 *DepoTech Corp.*, 149 F. Supp. 2d 1212, 1218 (S.D. Cal. 2001) (taking judicial notice of chart
 6 summarizing company's risk disclosures); *see also* Fed. R. Evid. 1006.

7 Exhibit 39 is a table summarizing defendants' stock sales and holdings of Connetics stock
 8 during the period of July 1, 2001 to July 9, 2006. It is based on judicially noticeable documents,
 9 principally Forms 4 filed by the individual Connetics defendants. *See* Exs. 24-26. Plaintiff does
 10 not contest the accuracy of Exhibit 39, but rather takes issue with its relevance, arguing that it is
 11 improper to include underwater options in calculating the defendants' holdings. However,
 12 plaintiff cites absolutely no authority whatsoever for this novel proposition. Rather, the law is
 13 clear than when evaluating a defendant's stock sales, a court must compare those sales to the
 14 defendant's total stock holdings, which includes exercisable stock options. *Silicon Graphics*, 183
 15 F.3d at 986-87. There is no basis in the case law to exclude so-called underwater stock options
 16 from that analysis. Moreover, plaintiff's proposed rule makes no sense. A defendant would have
 17 the same motivation to increase the share price (so that the options were no longer underwater)
 18 regardless. In any event, plaintiff never alleges what defendant's total holdings would be if so-
 19 called underwater stock options were excluded. Exhibit 39 is properly considered because it is
 20 based on documents that plaintiff admits are judicially noticeable, and there is no dispute that it is
 21 an accurate summary of these voluminous documents.

22 Exhibit 40 is a table summarizing some of the meaningful cautionary language related to
 23 Velac gel. It is based on judicially noticeable documents, namely public filings and statements.
 24 *See* Exs. 1, 3-8, 10-12, 17-18. Plaintiff's objection to this exhibit ignores that, with respect to
 25 forward-looking statements, the Reform Act explicitly provides that courts **must** examine the
 26 contents of public statements and the relevant cautionary language that applies to those
 27 statements. 15 U.S.C. § 78u-5(e). Moreover, with respect to oral statements during analyst calls,
 28 courts **must** examine the cautionary statements that are contained in written documents and SEC

1 filings referenced during the analyst calls. 15 U.S.C. § 78u-5(c)(2). Exhibit 40 properly excerpts
 2 the relevant cautionary language so that the Court can readily evaluate plaintiff's allegation that
 3 defendants intentionally deceived investors about Velac's prospects for FDA approval. As shown
 4 in Exhibit 40, defendants never promised that Velac would be approved, but rather repeatedly
 5 warned that FDA approval was uncertain and may be denied.

6 **IV. THE COURT SHOULD CONSIDER JUDICIALLY NOTICEABLE FACTS IN
 7 RULING ON THE MOTION TO DISMISS**

8 The remainder of plaintiff's opposition is spent arguing not over whether the Court may
 9 take judicial notice of the exhibits – it concedes that it can – but over “defendants’
 10 characterizations” of the documents and alleged “improper use of such documents.” RJN Opp. at
 11 1. As shown above, however, this argument is a red herring. The law requires the Court to
 12 review the documents and then consider inferences that can be drawn from those documents that
 13 refute plaintiff’s allegation of scienter. *See Tellabs*, 127 S. Ct. at 2509-11. Plaintiff cannot
 14 foreclose that analysis merely by arguing that it “opposes defendants’ characterization” of the
 15 document, or asserting that defendants are somehow misusing the documents by arguing that they
 16 eviscerate scienter. RJN Opp. at 1. Even before *Tellabs*, the Ninth Circuit rejected the argument
 17 that a court had to accept a plaintiff’s characterization of the facts and could not consider a
 18 defendant’s characterization when ruling on a motion to dismiss. *See Gompper*, 298 F.3d at 897.
 19 Now, after *Tellabs*, the law is clear that a court must consider and weigh a defendant’s
 20 characterization of factual allegations and judicially noticeable documents when deciding whether
 21 a plaintiff has pleaded a “cogent and compelling” inference of scienter. *See Tellabs*, 127 S. Ct. at
 22 2509-11.

23 For these reasons, the Court must take judicial notice of Exhibits 1, 2, 7, 8, 13-16 and 19
 24 and draw inferences from those documents that negate scienter under *Tellabs*.

25 **A. Exhibit 1– Transcript of Connetics’ April 26, 2005 Call**

26 Exhibit 1 is a transcript of Connetics’ April 26, 2005 conference call. Plaintiff relies on
 27 this transcript in the complaint and admits that the Court may take judicial notice of it. AC ¶¶ 78-
 28

1 79, 261-65; *see also* RJD Opp. at 4.¹ In that transcript, Connetics reports several facts that
 2 explain its actions and negate any inference that defendants knew at the time that the FDA would
 3 deny approval for Velac, including:

- 4 • “We conducted one of our preclinical studies in a transgenic mouse model. And in
 that study there was a positive response to our product. At the time, ***we carefully
 analyzed the results with a panel of leading experts in this model and leading
 toxicologists. The outcome of that was that the experts advised us that this mouse
 model is known to have limitations. And they concluded that the positive response
 was a result of one of these limitations of the model.***” Steskal Decl. Ex. 1 at 5
 (emphasis added).
- 5 • “Their advice is supported in fact, by other products which have had a positive finding
 in this model, resulting in a clinical hold only to be released later based upon
 submission of additional data. And in fact, ***benzoyl peroxide, a commonly used [over-
 the-counter] acne product and an ingredient in several prescription acne products
 has Rx labeling that notes a positive result in [a transgenic mouse] model.***” *Id.* at
 5-6 (emphasis added).
- 6 • ***“Because up to this point [the] FDA had not raised this issue with us, we were
 surprised to receive this information.*** However, we are in discussions with them on
 their questions. And we expect to submit additional information well before the
 PDUFA date which further supports our original conclusion.” *Id.* at 6 (emphasis
 added).
- 7 • ***“I would point out that as a rule, we do not feel it is appropriate frankly, to provide
 regular updates on our discussions with [the] FDA.”*** *Id.* (emphasis added).

8 Although plaintiff cites extensively from this conference call transcript in its complaint
 9 (AC ¶¶ 261-64), plaintiff now argues that the Court should ignore much of the transcript because,
 10 according to plaintiff, defendants’ statements are “fabrications.” RJD Opp. at 4. However,
 11 plaintiff pleads no facts – much less facts with particularity as required by the Reform Act –
 12 demonstrating that any of the statements are false or misleading. For instance, plaintiff does not
 13 allege that the expert panel did not conclude that the positive response in the mouse model “was a
 14 result of one of [the] limitations of the model,” *i.e.*, that it was a false positive. AC ¶ 261.
 15 Likewise, as shown, plaintiff does not allege that the FDA has not approved dermal products that
 16 had a positive response in the Tg.AC mouse model. In the absence of particularized allegations

17 ¹ Although plaintiff asserts that the authenticity of the transcript is in question at this point, it
 18 cannot both rely on and quote this transcript in its complaint and at the same time dispute its
 19 authenticity. *See Osher*, 308 F. Supp. 2d at 1186 (court must consider full document, not portion
 20 plaintiff “selectively quoted”); *Reiger*, 1999 WL 540893, at *2 (“the court may consider the full
 21 text of those documents, even when the complaint quotes only selected portions”); *In re
 Harmonic*, 163 F. Supp. 2d at 1086 (defendants may “attach to a 12(b)(6) motion the documents
 22 referred to in the complaint to show that they do not support plaintiff’s claim”).

1 demonstrating falsity under the Reform Act, the Court must accept the statements as true and
 2 draw inferences in defendants' favor. Here, the facts demonstrate that defendants reasonably
 3 believed that Velac could be approved by the FDA despite the positive response in the Tg.AC
 4 mouse model. *See Tellabs*, 127 S. Ct. at 2509-10 (holding that courts must engage in
 5 comparative analysis that credits inferences favorable to defendants); *Applied Micro Circuits*
 6 *Corp.*, 2002 U.S. Dist. LEXIS 22403, at *12 (where plaintiff "refer[s] to [] SEC filings in its
 7 amended complaint, [] it cannot therefore selectively argue that Defendants' cannot rely on the
 8 same material").

9 **B. Exhibit 2 – Transgenic Mouse Models Article**

10 Exhibit 2 is an article titled "Transgenic Mouse Models: Their Role in Carcinogen
 11 Identification." Plaintiff quotes this document and relies on it in the complaint to show that
 12 mouse studies make "correct" calls 77 to 81 percent of the time (and, by inference, make
 13 "incorrect" calls 19 to 23 percent of the time). AC ¶ 56. Plaintiff further agrees that the Court
 14 may take judicial notice of the fact that transgenic mice are engineered so that tumors will
 15 develop more quickly. RJN Opp. at 5. However, plaintiff takes issue in its opposition with the
 16 following statements that are also included within the article:

- 17 • "Overall, the transgenic models performed well, but important issues of validation and
 standardization need further attention to permit their regulatory acceptance and use in
 human risk assessment." Steskal Decl. Ex. 2 at 3.
- 19 • "Although they have great promise, transgenic models also have actual or potential
 limitations for use in a carcinogen identification effort. For example, many current
 transgenic models (including those evaluated here) have mutations in only one
 pathway that may, or may not, be relevant to human cancer processes for a given
 chemical. In addition, the specific gene defect may influence tumor development and
 type, increasing the difficulty of modeling the human response." *Id.* at 5.

23 But again, there is nothing in the complaint that disputes these facts. AC ¶¶ 54, 56.
 24 Indeed, plaintiff itself relies on the same article for its truth. *Id.* ¶ 56. Moreover, Exhibit 2
 25 demonstrates that there are known limitations to the transgenic mouse model, and positive results
 26 in Tg.AC mice may not be relevant to human cancer processes. Exhibit 2 is particularly relevant
 27 here because an expert panel told Connetics that Velac's positive response in the mouse model
 28 "was a result of one of these limitations of the model." AC ¶ 261. Thus, the Exhibit fully

1 corroborates the conclusions of the expert panel, namely, that the results of the mouse test were a
 2 false positive. The Court must take judicial notice of these facts in evaluating whether plaintiff
 3 has alleged a “cogent and compelling” inference of scienter. *See Tellabs*, 127 S. Ct. at 2509.

4 **C. Exhibits 7, 8, 13-16 and 19 – SEC Filings**

5 Finally, plaintiff argues that the Court may not consider SEC filings that plaintiff itself
 6 cites and relies on in its complaint. However, here again, plaintiff alleges disputes where there
 7 are none and asks the Court to ignore judicially noticeable documents in evaluating scienter.

8 *Exhibit 8.* Plaintiff does not assert that Exhibit 8 – a May 14, 2002 press release from
 9 Connetics – contains any false or misleading statements. AC ¶¶ 52-80; *see also* AC ¶ 41 (quoting
 10 press release). There is absolutely no allegation in the complaint that the statement that “clinical
 11 studies in more than 700 patients in Europe … have shown Velac gel to be safe and effective as
 12 leading topical treatments,” was either false or misleading. *See* Ex. 8; AC ¶¶ 52-80. In fact,
 13 those statements were made before the class period and thus could not form the basis of any
 14 claim. Moreover, the European clinical tests showing that Velac was safe for human use are
 15 highly relevant in assessing whether plaintiff has alleged a “cogent and compelling” case that
 16 defendants in fact knew that Velac could never be approved. *See In re Invision Tech., Inc. Sec.*
 17 *Lit.*, 2006 WL 538752, *2 (N.D. Cal. Jan. 24, 2006) (statements outside class period are not
 18 actionable but considered only in context of demonstrating “truth of falsity of Class Period
 19 statements”); *DeMarco*, 149 F. Supp. 2d at 1223 n.6 (statements before the class period “may
 20 have evidentiary relevance to the issue of scienter”). In fact, these European clinical test results
 21 are consistent with the results of the Phase III clinical trials in the United States which involved
 22 testing on 2,200 patients. AC ¶¶ 36, 44-48, 255; Steskal Decl. Ex. 6, at 6 & Ex. 7, at 10. Thus,
 23 the prior clinical studies in Europe, like the Phase III clinical trials in the United States, are
 24 relevant to the scienter of defendants. Those tests demonstrate that defendants had compelling
 25 reasons to be optimistic that Velac could be approved by the FDA.

26 *Exhibit 7.* Plaintiff likewise does not allege in its complaint that Exhibit 7—a July 25,
 27 2006 Form 10-K/A SEC filing—contains any false or misleading statements. In fact, plaintiff
 28 repeatedly cites that filing for the truth. AC ¶¶ 130-32. Moreover, that Form 10-K/A was issued

1 *after* the end of the class period and thus cannot form the basis of plaintiff's fraud claim. AC ¶
 2 27 (class period ends on July 9, 2006); *see also Invision Tech.*, 2006 WL 538752, at *2;
 3 *DeMarco*, 149 F. Supp. 2d at 1223 n.6. Given these express allegations in the complaint, plaintiff
 4 cannot conceivably argue (as it now attempts to do in its brief) that the Form 10-K/A contains
 5 "false" factual assertions. In any event, there is no allegation in the complaint that disputes the
 6 fact that "until December 2005 the reports received [from Connetics' distributors] contained
 7 inaccuracies and inconsistencies that made them unreliable." Ex. 7 at 31; AC ¶¶ 109-120. In
 8 fact, despite the fact that Connetics publicly disclosed that it received inventory reports from its
 9 distributors, plaintiff never explains how Connetics could have engaged in fraudulent channel
 10 stuffing if those reports did not show a backlog of inventory.

11 *Exhibits 13, 14, 16 and 19.* Plaintiff fails to allege with any specificity that any statement
 12 contained or relied on in Exhibits 13, 14 and 19 was either false or misleading. AC ¶¶ 201-204,
 13 217-220, 282-286. Instead, plaintiff block quotes from these press releases and generically
 14 alleges that these statements were "materially false and misleading" for unstated reasons
 15 purportedly having something to do with plaintiff's allegations of channel stuffing. *See, e.g.*, AC
 16 ¶¶ 204, 220, 286. This type of "puzzle pleading" is not sufficient to plead securities fraud under
 17 the Reform Act. 15 U.S.C. § 78u-4(b)(1)(B); *see also In re Splash Tech. Holdings, Inc. Sec.*
 18 *Litig.*, 160 F. Supp. 2d 1059, 1075 (N.D. Cal. 2001) (this type of pleading "obfuscates rather than
 19 clarifies" and fails to "divine precisely which statements (or portion of statements) are alleged to
 20 be false or misleading, and the reason or reasons why each statement is false or misleading").
 21 (quotation omitted)

22 In any case, the Court may take judicial notice of these press releases and consider them
 23 for the purpose of evaluating whether plaintiff's inference of scienter is cogent and compelling
 24 under *Tellabs*. In fact, there is nothing in the complaint that disputes any of the following:

- 25 • Connetics submitted an NDA application for Velac to the FDA in August 2004, which
 was accepted in October 2004. *See Steskal Decl.* Exs. 14-15.
- 26 • There is a user fee associated with an NDA application. *See id.* Ex. 15.
- 27 • Connetics paid \$3.5 million to Yamanouchi Europe BV in conjunction with its
 submission of the Velac NDA to the FDA. *See id.* Exs. 14, 16.

- 1 • In Q4 2004, Connetics hired 66 sales professionals, more than doubling its sales force.
 2 See *id.* Ex. 16.

3 The Court may take judicial notice of these facts—and may draw inferences from them, including
 4 the reasonable inference that Connetics incurred substantial expenses in seeking FDA approval
 5 for Velac and preparing to launch Velac. Far from supporting an inference of fraud, these facts
 6 demonstrate that defendants actually believed that Velac could obtain FDA approval. See
 7 *Tellabs*, 127 S. Ct. at 2510; *see also In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1118 (9th
 8 Cir. 1989) (scienter dispelled by efforts to prepare product for launch).

9 **V. THE COURT SHOULD TAKE JUDICIAL NOTICE OF EXHIBIT 42**

10 Defendants also request judicial notice of Exhibit 42, which is attached to the
 11 Supplemental Declaration of Christopher Steskal. Exhibit 42 is a transcript of a January 25, 2005
 12 conference call that was incorporated by reference in the complaint. AC ¶¶ 241-245. In its
 13 complaint, plaintiff engages in impermissible “puzzle pleading” by citing numerous statements
 14 and then alleging in conclusory fashion that the statements are “false or misleading.” AC ¶ 146-
 15 332. In its opposition to the motion to dismiss, plaintiff reaches back to paragraph 242 of the
 16 complaint and quotes one such statement from the January 25, 2005 conference call. Opp. at 4,
 17 11-12 (citing AC ¶¶ 242-245). However, plaintiff wrongly cites the statement out of context.
 18 Contrary to plaintiff’s suggestion, defendants Wiggins and Higgans were not discussing whether
 19 Velac would be approved by the FDA during that call, but rather whether (if it were approved) it
 20 could compete against other products on the market. In particular, when an analyst asked about
 21 “potential competitors to Velac,” defendant Wiggins stated that “we’re very confidant in the data
 22 set we got.” Supp. Steskal Dec. Ex. 42 at 17-18; *see also id.* at 3 (“[O]ur planning case is that
 23 there will be a competitive product for Velac but we have excellent data on Velac.”).

24 To give context to the quoted statements, defendants request that the Court take judicial
 25 notice of Exhibit 42. *See Cooper v. Pickett*, 137 F.3d 616, 623 (9th Cir. 1997) (court may
 26 consider document referenced in complaint); *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994)
 27 (same). When read in context, the statements during the January 25, 2005 conference call show
 28 that defendants actually believed Velac could be brought to market and that they were making

1 plans and investing resources to do just that. *See Apple Computer*, 886 F.2d at 1118. Moreover,
 2 it is undisputed that the Phase III clinical trials and European clinical trials demonstrated the
 3 efficacy of Velac and provided ample reason to be confident in Velac's ability to compete. In any
 4 event, the law is clear that generalized assertions of corporate optimism (*e.g.*, "excellent results")
 5 are too vague and unspecific to be actionable under the securities laws. *See In re Cornerstone*
 6 *Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005); *see also In Re*
 7 *Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 162 (D. Mass. 2007) ("Every company
 8 praises its products and its objectives, and these statements are nothing more than corporate
 9 puffery.").

10 **VI. CONCLUSION**

11 For the reasons stated herein and in defendants' Request for Judicial Notice, the Court
 12 should grant judicial notice of Exhibits 1 to 42 of the Declaration and Supplemental Declaration
 13 of Christopher Steskal.

14 Dated: October 4, 2007

Respectfully submitted,

15 FENWICK & WEST LLP

17 By: /s/ Christopher J. Steskal
 18 Christopher J. Steskal

19 Attorneys for Defendants Connetics Corp.,
 20 John L. Higgins, Lincoln Krochmal,
 C. Gregory Vontz, and Thomas G. Wiggans

25251/00402/LIT/1273476.3

PROOF OF SERVICE

The undersigned declares as follows:

I am a citizen of the United States and employed in San Francisco County, State of California. I am over the age of eighteen years and not a party to the within-entitled action. My business address is Fenwick & West LLP, San Francisco California, 555 California Street, 12th Floor San Francisco, California 94104. On the date set forth below, I served a copy of the following document(s):

**REPLY MEMORANDUM IN SUPPORT OF REQUEST FOR JUDICIAL
NOTICE BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS,
LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS**

on the interested parties in the subject action by placing a true copy thereof as indicated below,
addressed as follows:

Victor E. Zak
24 Oakmont Road
Newton Center, MA 02459

BY OVERNIGHT COURIER: by placing the document(s) listed above in a sealed envelope with a prepaid shipping label for express delivery and causing such envelope to be transmitted to an overnight delivery service for delivery by the next business day in the ordinary course of business.

17 I declare under penalty of perjury under the laws of the State of California and the United
18 States that the above is true and correct.

Date: October 4, 2007

/s/ Margaret E. Vertin

Margaret E. Vertin